

Claims

CM What is claimed is:

1. A stabilized gonadotropin containing lyophilisate comprising:
a dicarboxylic acid salt stabilizer in admixture with a gonadotropin capable of stabilization by the amount of stabilizer present in the lyophilisate.
2. The stabilized gonadotropin containing lyophilisate of claim 1 further comprising a non-reducing sugar, wherein the non-reducing sugar is present in an amount three to fifty times that by weight of the dicarboxylic acid salt stabilizer.
3. The stabilized gonadotropin containing lyophilisate of claim 1 further comprising a non-ionic surfactant.
4. The stable lyophilisate of claim 3 wherein said gonadotropin is selected from the group consisting of luteinizing hormone, human chorionic gonadotropin, follicle stimulating hormone, or mixtures thereof.
5. The stable gonadotropin containing lyophilisate of claim 4 wherein said dicarboxylic acid salt stabilizer is a salt of citric, tartaric, or aspartic acid.

Sub. 82
The stabilized gonadotropin containing lyophilisate of claim 6 wherein the non-reducing sugar is present in an amount three times that by weight of the dicarboxylic acid salt stabilizer.

Sub. 84
The stable gonadotropin containing lyophilisate of claim 7 further comprising a second gonadotropin capable of stabilization by said dicarboxylic acid salt stabilizer.

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8.
A stabilized gonadotropin containing lyophilisate comprising:

one part by weight of a gonadotropin; and
200 to 10,000 parts by weight of a dicarboxylic acid salt stabilizer associated with said gonadotropin.

9.
A method of making a stabilized gonadotropin lyophilisate comprising:

admixing, in an aqueous solution, at least one gonadotropin with an amount of dicarboxylic acid salt to adjust the ionic strength of said solution to between 0.050 and 0.350,

dissolving a non-reducing sugar in said admixture in an amount of about three to fifty times the amount, by weight, of the dicarboxylic acid salt, and
freeze-drying said admixture at a temperature greater than -35° centigrade to form said stabilized gonadotropin lyophilisate.

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